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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,280	12/12/2003	Tom Tsang	246392US20CONT	8225

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ALEXANDRIA, VA 22314

EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/733,280	<b>Applicant(s)</b> TSANG ET AL.	
	<b>Examiner</b> Scott D. Priebe, Ph.D.	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 47-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>20031212</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for methods of using the recited expression construct to effect expression of a selected polynucleotide in a mammalian cell, does not reasonably provide enablement for a method of using the expression construct in cells other than mammalian cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 47-57 are broadly directed to methods of expressing a polynucleotide in any eukaryotic or prokaryotic cell or in any type of subject following heat induction of the heat shock promoter. However, the guidance in the specification is directed solely to carrying out the claimed invention in mammalian cells and subjects (therapy). See for example, section "6. Cell Targets" (pg. 47), which names only mammalian cells as suitable target cells. The specification does not teach either implicitly or explicitly that the claimed methods can be practiced on non-mammalian cells, or non-mammalian subjects. All of the vectors described in section 5 are for expression in mammalian cells. Most of the disclosure of the selected polynucleotides relates to therapeutic use in mammals.

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In view of the lack of guidance or working examples relating to the use of the claimed invention with non-mammalian cells or subjects, the specification leaves it entirely to one of skill in the art to develop the invention for non-mammalian cells or subjects. The specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. *In re Goodman*, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing *In re Vaeck*, 20 USPQ2d at 1445 (Fed. Cir. 1991). Consequently, the specification fails to enable the claimed invention as broadly as it is claimed.

Applicant's arguments filed 6/28/04 have been fully considered but they are not persuasive. The arguments do not address one of the issues raised in the parent application, that of the appropriate cell-type, i.e. mammalian, upon which the method is to be practiced. With respect to the remaining grounds of rejection presented in the parent application, Applicant's arguments, particularly that the claimed method could be used to evaluate potential therapeutic genes *in vivo*, is convincing. Consequently, the full rejection set forth in the parent application has not been repeated here.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,709,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to the method for which the expression construct claimed in the '858 patent was developed, and for which one of skill in the art would expect to use the product, i.e. for transfection of mammalian cells.

Claims 47-57 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/108,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace embodiments of the '486 claims, wherein the second promoter is an HIV-2 ITR (claim 5 of '486) and the transactivator is HIV tat (claim 12 of '486).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, the '486 application has been allowed and the issue fee paid, and upon issue this rejection will no longer be provisional.

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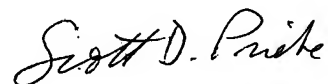
Claims 47-57 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-44 of copending Application No. 10/152,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace embodiments of the '577 claims, wherein the second promoter is an HIV-2 promoter and the transactivator is HIV tat (see claims 23 and 24 '577).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. However, the '577 application has been allowed and the issue fee paid, and upon issue this rejection will no longer be provisional.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.  
Primary Examiner  
Art Unit 1633